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Deliverable abstract

This Progress report describes SEMPAs progress in refactoring and/or developing new national IT-systems regarding Substances, Medicinal Products, Organisations and Referentials (SPOR) including EMA SPOR-interoperability, automation where possible and implementation of IDMP according to three main business objectives.

SEMPAs national program SPIRA (Substances, Products, Intressent (Organisation), Referentials, Automation) started in 2018 with the above-described scope. We are now executing a project that is aligned with business and stakeholders. The project has a roadmap with defined milestones, business objectives and an agile stepwise approach in two major phases. In the end of 2020, the progress has reached following state:

- Substances: are regularly being cleansed and work is aligned with UNICOM WP2.
- Products: new national IT-system, EIRA, have been launched with modules for management for Substitution and Composition. Work is according to plan with modules for Packaging, Medicinal Product data and Invoicing with multiple launches in 2021, 2022 and 2023. Work is planned in order to meet UPD (Union Product Database) requirements.
- Organisations; are regularly being cleansed. Preparations to meet UPD requirements which will be a fundament also for the human medicines. A new national IT-system is being developed and will be launched Q1 2021.
- Referentials; are regularly being aligned with EMA Referentials.
- IDMP; Business Objectives have been set in general and Readiness Review have been performed. Harmonisation to IDMP is incorporated in EIRA in at stepwise approach. The Business Objectives are divided in three groups:
 - A) Regulatory interoperable within the community of EMA and Member States
 - B) SEMPAs internal Business Needs
 - C) National benefits within Swedish Healthcare, Pharmacies, and eHealth. Up until 2020, work have been focused on Business Objectives in A and B.

Keywords: SEMPA, IDMP, Implementation, SPOR, SPIRA, EMA, Sweden, ISO

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TABLE OF CONTENTS

Revision history	2
Deliverable abstract.....	3
List of abbreviations.....	5
1 Executive summary	7
2 SEMPA, Swedish Medical Products Agency	8
2.1 Role of SEMPA in Swedish eHealth eco-system	9
3 Task 4.9 Progressing ISO IDMP implementation at SEMPA in Sweden	10
3.1 Business Objectives	10
3.2 Description of the IDMP implementation program SPIRA.....	11
3.3 EIRA system architecture and tools	12
3.4 IDMP logical model assessment SEMPA.....	14
3.5 Phased approach and transition strategy	17
3.6 Status and deliverables	18
3.7 Plan forward.....	18
4 Best practises and lessons learned	20
4.1 Experience with SPOR API	20
4.2 Experience with RMS	20
4.3 Experience with SMS	20
4.4 Experience with OMS	20
5 Challenges, risks, and mitigations.....	21

LIST OF FIGURES

Figure 1. SEMPA offices in Uppsala, Sweden	8
Figure 2. SEMPA product registry in the eHealth eco-system	9
Figure 3. SEMPA initial IDMP Implementation Roadmap	12
Figure 4. SEMPA IDMP Implementation Program Plan	12
Figure 5. From monolithic LVIS GK to modular EIRA	13
Figure 6. From monolithic LVIS GK to modular EIRA	13
Figure 7. Example of the GUI of EIRA	14
Figure 8. Logical model for assessment of EIRA	15
Figure 9. Assessment criteria and descriptions.....	15
Figure 10. IDMP readiness assessment results, October 2020.....	16
Figure 11. IDMP readiness assessment results, goal in 2023	16
Figure 12. Implementation part 1 strategy.....	17
Figure 13. Implementation part 2 strategy, de-commissioned legacy system	18

List of abbreviations

Abbreviation	Complete form
.Net	.NET (pronounced dot net) is a framework that provides programming guidelines that can be used to develop a wide range of applications
ADR	Adverse Drug Reaction
API	Application Programming Interface
CTS	Communication and Tracking System
DB	Database
eAF	Electronic Application Form
EIRA	SEMPAs new medical product registry. The name EIRA comes from the goddess of medical skills in Norse mythology
EMA	European Medicines Agency
HMA	Heads of Medicines Agencies
IDMP	Identification of Medicinal Products
ISO	International Organization for Standardization
LVIS GK	Läkemedelsverkets informationssystem Godkännande (SEMPA information system, assessment)
MS	Member State
MVP	Minimum Viable Product
NCA	National Competent Authority
NPL	National Product Registry
OMS	Organisation Management Services
PMS	Product Management Services
RALF	Referensdata Administration under Läkemedelsverkets Förvaltning (reference data administration tool for SEMPA)
RMS	Referentials Management Services
SCRUM	Scrum is an agile framework for developing, delivering, and sustaining complex products. The term is borrowed from rugby, where a scrum is a formation of players.
SEMPA	Swedish Medical Products Agency
SMS	Substance Management Services
SPIRA	SPIRA is SEMPAs SPOR-program with development projects and aligned business, and incorporated change and transition. SPIRA is an acronym and stands for Substances, Products, Intressent (Organisation), Referentials, Automation
SPOR	EMA service delivering quality data management services for substances, products, organisations and referentials (SPOR) to power EU regulatory activities. The four SPOR data management services are: SMS, PMS, OMS, RMS

TOM	Target Operating Model
UPD	Union Product Database, a Union database on veterinary medicinal products
VB6	Visual Basic 6
WP	Work Package
WP2	UNICOM Work Package 2, Implement IDMP – Substance Management in Europe
WP3	UNICOM Work Package 3, Pan-European IDMP compliant application forms

1 Executive summary

This document describes SEMPAs plan and progress regarding Task 4.9 Progressing ISO IDMP implementation at SEMPA in Sweden. SEMPAs plan is described regarding business objectives, road map, challenges, and continuous work. Progress is described in the roadmap and as summary of deliverables regarding 2020, 2021, 2022 and 2023.

In order to implement ISO IDMP standards at NCAs level, preparatory work on IT systems and existing medicinal product data repositories is necessary. This preparation is a prerequisite to be able to provide ISO IDMP compliant data to health service providers, including eHealth organisations.

Relevant implementation tasks are carried out in Work Package (WP) 4 related tasks, in which 11 national competent authorities have setup local implementation projects to implement new IDMP compatible systems or to refactor existing software systems towards IDMP.

As part of Task 4.9 SEMPA will build a new database, EIRA (SEMPAs new medical product registry), replacing a legacy system, which is used for medicinal product marketing authorisation and licensing. The new system EIRA is also a central database that provides data flows to other IT systems used by national health service providers.

We started our mapping and cleansing activities on organisations and referentials lists, as Organisations Management Service (OMS) and Referentials Management Service (RMS) are currently two live SPOR services provided by EMA.

We have mapped and cleansed all active marketing authorisation holders and NCAs in our current database. This work included submitting several change requests to change the names and addresses of Swedish companies as well reporting data discrepancies through the EMA service desk.

We have finished mapping of several referentials lists (e.g Pharmaceutical Dose Form, Combined Pharmaceutical Dose Form, Combination Package, Combined Term, Country, Special Precaution for Storage) and reported found quality issues to EMA.

The next updates of this document are expected in month M26; M38 and M48.

2 SEMPA, Swedish Medical Products Agency

The Swedish Medical Products Agency is the national authority responsible for regulation and surveillance of the development, manufacturing and sale of pharmaceuticals and other medicinal products.

With 850 employees, SEMPA has offices in two locations, Uppsala and Stockholm, Sweden.



Figure 1. SEMPA offices in Uppsala, Sweden

Areas of responsibility

- ▶ Medicinal Products (pharmaceuticals)
 - ▶ Regulatory Authority on clinical trials and medicinal products
 - ▶ Trading with pharmaceuticals; permission, approval and control
 - ▶ Effective use
 - ▶ Safety, ADR-reporting
- ▶ Cosmetics, Narcotics
- ▶ Medical Devices
- ▶ Swedish Poisons Information Centre (24/7 service)
- ▶ Information provider
 - ▶ to Swedish Healthcare and pharmacies regarding structured data for medicinal products and substances

Key figures

- ▶ Number of Medicinal products
 - ▶ Licensed 14 000, in Swedish National Registry including withdrawn approx. 30 000
- ▶ Number of Substances
 - ▶ In Swedish National Registry 7 000 (published)
- ▶ Number of Organisations
 - ▶ Approx. 5 300 organisations with current or previous relations to products with some 7 300 locations/addresses
- ▶ Number of Referential Lists
 - ▶ Local system contains approx. 200 Referential Lists, approx. 30 have RMS-mappings

IT at SEMPA

SEMPA's IT team consists of 78 employees, supported by some external contractors and service providers. For core business processes, tailor made applications are used. Business experts are very much engaged in all data model and processes' analysis workshops, majority of departments and divisions dedicated business experts that are assigned on custom application development projects. The development is mainly done in house with internal staff.

2.1 Role of SEMPA in Swedish eHealth eco-system

The medicinal product database at SEMPA has been live since the early 1980s and feeds the national public product registry since 2004. It is the single source of truth providing approved product information to the over 1400 pharmacies, the Swedish eHealth agency and further to the Swedish eHealth eco-system.

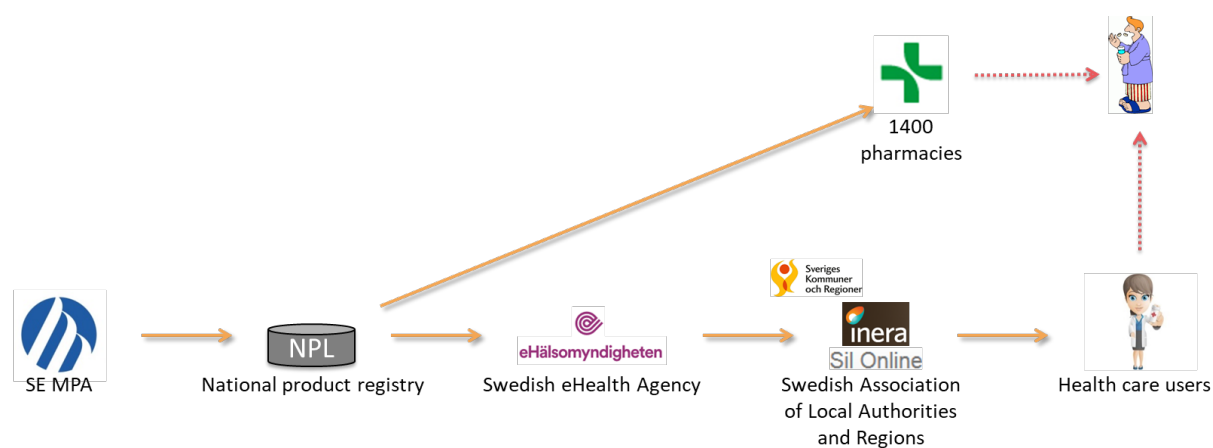


Figure 2. SEMPA product registry in the eHealth eco-system

3 Task 4.9 Progressing ISO IDMP implementation at SEMPA in Sweden

The Commission Implementing Regulation (EU) No 520/2012 (articles 25 and 26) states that European Union (EU) Member States, marketing authorisation holders and EMA shall make use of the ISO IDMP standards.

NCA's at national level are responsible to maintain medicinal product data and in many members states NCA's also provide medicinal product master data to eHealth providers. In order to implement ISO IDMP at national level, preparatory work on IT systems and medicinal product data repositories is necessary.

Implementation of ISO IDMP at NCA's is performed in national implementation projects where UNICOM funding is a financial contribution in addition to the national investments. The participation in UNICOM enables faster national implementation and supports necessary collaboration.

This report is a status update on UNICOM Task 4.9: Progressing ISO IDMP implementation at SEMPA in Sweden.

The task is a contributing part to a national program that will design, develop and implement new national drug register (SEMPA-EIRA) based on ISO IDMP and national demands for medicinal products and organisations. The system will be the primary source of Medicinal Product information for the National Health Service.

SEMPA will implement data connections to EMA's SPOR services where appropriate, to support automation of data entry into internal databases, and support interoperability between internal and EMA systems.

The national program also includes migration of national master data to be able to process, consume and provide IDMP/SPOR compatible data. Legacy data for medicinal products will be migrated to the new database according to European wide agreed migration rules (EU IDMP Implementation Guide).

The development of the new drug information platform and systems will be done in house.

The next updates of this document are expected in month M26; M38 and M48.

3.1 Business Objectives

In the end of 2023, SEMPA maintains the master data sources within SPIRA in a way that:

- ▶ Has reduced operational risks with current legacy system and discontinued the entire LVIS
- ▶ Is useful (efficient, effective and user-friendly)
- ▶ Contributes to higher efficiency in the business, support and IT systems management
- ▶ Provides a balanced level of data quality and information security
- ▶ Has a relevant part of the information structure adapted to IDMP
 - ▶ Regulatory interoperability
 - ▶ SEMPA's own Business Objectives
 - ▶ National Objectives regarding eHealth, Healthcare and Pharmacies

Mission statement

The overall goal is to renew and refactor SEMPA's marketing authorization and medicines register LVIS with an IDMP compatible EIRA system.

- ▶ Replace SEMPA Product and Organisation Registry (LVIS) by developing new system EIRA for the master data sources Pharmaceutical products and Organisation, on a modern technical platform, and adapt relevant parts of the information structure to IDMP.
- ▶ Discontinue affected parts of LVIS and its Microsoft VB6 technology.
- ▶ Develop and streamline business operations and information management as well as automate the entry of information where it provides relevant benefits.

3.2 Description of the IDMP implementation program SPIRA

SPIRA is SEMPAs SPOR-program with development projects and aligned business, and incorporated change and transition

SPIRA is an acronym and stands for **S**ubstances, **P**roducts, **I**ntressent (Organisation), **R**eferentials, **A**utomation (automation will be done where possible)

The program includes the following sub-tasks:

- ▶ Plan and design the IDMP compliant medicines register
 - ▶ Gap analysis of current data model against the IDMP implementation guide
 - ▶ Identify needed changes
 - ▶ Design the new phase I data model
- ▶ Plan implementation and data migration
- ▶ Implementation of the new medicines register
- ▶ Data migration
- ▶ Cleansing of the legacy data

The work started by designing a new IDMP compatible system to replace the 20-year old marketing authorization and medicines register LVIS GK. The whole infrastructure of LVIS, including the database, software, and servers, will be replaced by a new register architecture EIRA based developed in .Net.

At the beginning of the UNICOM project, not all necessary building blocks for IDMP implementation nor the EU IG V2 (EU IDMP Implementation Guide version 2) were available for the partners. Therefore, construction of the EIRA system was decided to be made in stages. First, the evaluation and gap analysis of the current data model was done against the ISO IDMP standard documentation. At this phase, RMS and OMS related data model changes were performed but elements that were related to parts still missing from SPOR data, as for example SMS and PMS related changes, were left untouched. Due to the several data model changes, the conversion of the legacy data required substantial amount of work. For example, some of the data in the LVIS system was contained in documents and csv-files that needed to be converted into a form compatible with the EIRA database

In Sweden, the marketing authorization and medicines register serves as the master data source of medicines and, importantly, is also utilized by many national applications.

In summary, we have built the foundation of the new EIRA registry during the first year of the project (2019). The first parts of EIRA was launched in 2019, the development will continue, and additional functionality will be delivered and put in production in stages. When the implementation guideline becomes available, the work continues by gradual implementation of the remaining data model changes (SMS and PMS) and mapping the legacy data with the RMS terms and the OMS information.

SPIRA program roadmap (subject to regular revision each quarter):

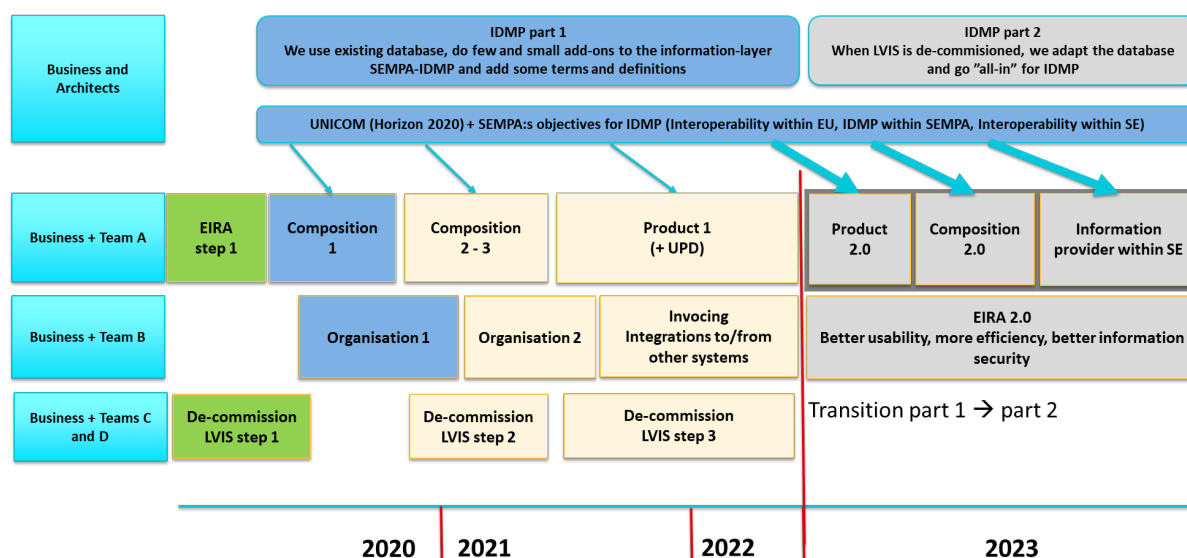


Figure 3. SEMPA initial IDMP Implementation Roadmap

Original overall program plan (due to the Covid-19 pandemic and the related additional tasks and responsibilities put upon SEMPA the program is likely to changed and delayed in some areas):

			2019			2020			2021			2022		
SPIRA	Area	Goals	T1	T2	T3	T1	T2	T3	T1	T2	T3	T1	T2	T3
S	Substance	Replace LV:s substance DB LSA with an IDMP DB												
P	Basic functionality	Basic functionality GUI (front-end), back-end, DB-implementation, roll-based accesskontroll, logging, archiving			MVP1	MVP2	MVP3							
P	Generic substitution	Replace functionality in LVIS GK for management of generic substitution decisions, refine work processes. Two step: MVP and then increased functionality.			MVP									
P	Information services	New IT-environment for Crystal Reports, Windows 10, QlikView, Office2016. Establish design guidelines.												
P	Integrations	See over existing integrations, design "to-be" situation, establish guidelines.												
P	Packaging	Replace functionality in LVIS GK for management of packaging including IDMP structures.							MVP					
P	Ingredients	Replace functionality in LVIS GK for management of ingredients including IDMP structures.							MVP					
P	Medicinal product	Replace functionality in LVIS GK for management of core product information including IDMP structures.									MVP			
P	Invoicing	See over LV:s needs in general. Replace functionality in LVIS GK for management of annual fees for medicinal products.		Pre-study								MVP		
P	New binder management	Replace the function in LVIS GK for management (check out, check in) of old binders containing paper documentation.												
P	Decommission LVIS GK Case	Decommission completely case management in LVIS GK - partial replacement occurred earlier. Make sure reporting functionality based on cases is taken care of.												
P	IDMP for NPL	Start export of IDMP based medicinal product information to the health care sector via NPL.												
I	Intressent (Organisations)	Replace functionality in LVIS GK for management of organisations including integration with OMS and version management.			Pre-study					MVP				
R	Decommission LVIS BAS	Update RALF (LV:s RMS) so that LVIS Base can be decommissioned.												
A	Increased automation (eAF, CTS)	Deliver new automation functionality for the consumption of more of the eAF. Integrate with CTS.					MVP				MVP			

Figure 4. SEMPA IDMP Implementation Program Plan

3.3 EIRA system architecture and tools

SEMPA will replace the legacy system LVIS GK which was a big monolithic Visual Basic 6 system in use since the late 1990's built upon an Oracle database (the original information model is still very usable and will be reused) with a new system EIRA.

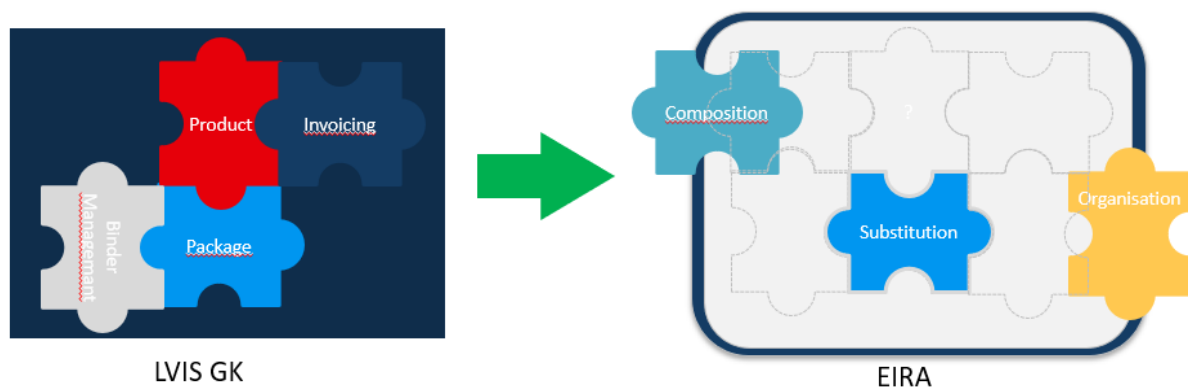


Figure 5. From monolithic LVIS GK to modular EIRA

The architecture of the new system EIRA will be tiered based built upon the original Oracle DB with a layer of microservices that connects through web applications to various clients and other systems. The system EIRA will be built on new technology: .Net Core for server-side logic and Angular for client-side logic.

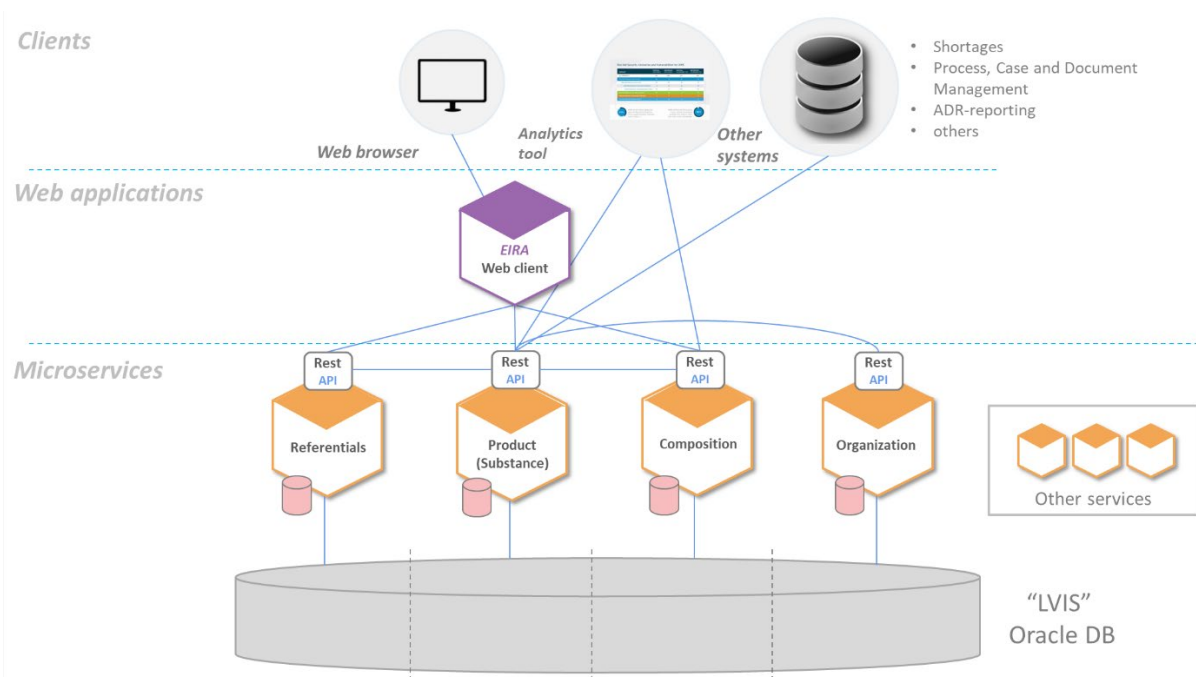


Figure 6. From monolithic LVIS GK to modular EIRA

The end user graphical interface will be web based and built according to the SEMPA graphical profile, example below.

The screenshot shows the EIRA Test web application. At the top, there's a search bar with the text 'para tabl 500' entered. Below the search bar, a table titled 'Sökresultat' displays search results. The table has columns: Substansgrupp, Läkemedelsformgrupp, Styrkegrupp, Antal produkter, and Kort beskrivning. The results list various combinations of Paracetamol and Kodein in different forms and strengths. Below the search results, there's a 'Detaljer' section showing details for 'Paracetamol + kodein' in 'Tablett' form, with a strength of '500 mg/30 mg (ERP Solpadol från UK)'. It also shows a list of products with columns: ASP-nr, Produktnamn, Läkemedelsform, Styrka, MAH, Utförselland, Produktstatus, and Utb status.

Substansgrupp	Läkemedelsformgrupp	Styrkegrupp	Antal produkter	Kort beskrivning
Paracetamol	Brustablett	500 mg (Accord)	0	
Paracetamol + kodein	Tablett	500 mg/30 mg	5	
Paracetamol + ibuprofen	Tablett	500 mg/150 mg	1	
Paracetamol + kodein	Brustablett	500 mg/30 mg	6	
Paracetamol	Tablett	500 mg	31	Kort beskrivningstext
Paracetamol + kodein	Tablett	500 mg/30 mg (ERP Solpadol från UK)	1	
Paracetamol	Tablett (Zapp)	500 mg	0	
Paracetamol + koffein	Tablett	500 mg/65 mg (grupp B)	1	
Paracetamol + koffein	Tablett	500 mg/65 mg	3	
Paracetamol + koffein	Brustablett	500 mg/65 mg	1	

ASP-nr	Produktnamn	Läkemedelsform	Styrka	MAH	Utförselland	Produktstatus	Utb status
2014-0138	Paracetamol/Kodein Actavis	Filmraderad tablett	500 mg/30 mg	Actavis Group PTC ehf.		Änregistrerad	Kandidat

Figure 7. Example of the GUI of EIRA

In the development phase we are utilising a lot of tools, worth mentioning are:

- ▶ Data cleansing, Organisations; SPORIFY
- ▶ API testing; Swagger
- ▶ Data model; Enterprise Architect
- ▶ Database; Oracle
- ▶ System Development; Azure DevOps, .NET Core, Angular, Elastic Search, QlikView

3.4 IDMP logical model assessment SEMPA

To assess the IDMP readiness of the SEMPA EIRA database, we have performed an IDMP readiness review where we have looked at “to what extent does the current SEMPA product database support IDMP”.

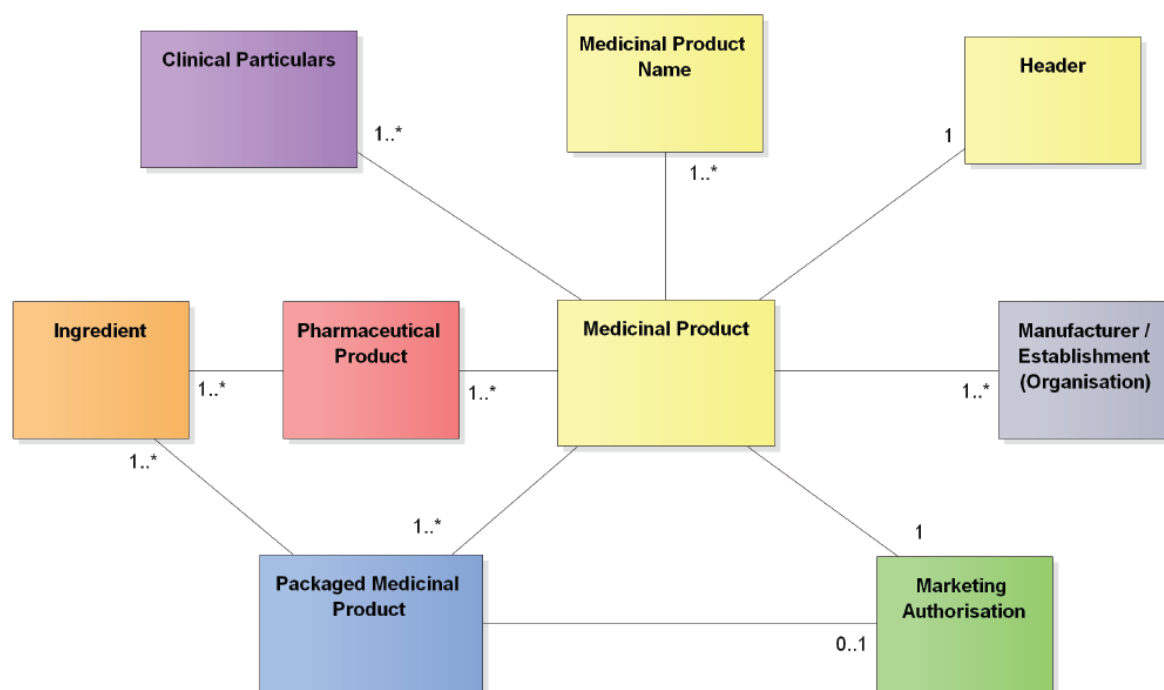


Figure 8. Logical model for assessment of EIRA

The EIRA system has been analysed in relation to the logical model according to the following criteria:

- ▶ Structure
- ▶ Terminology
- ▶ Data

Assessment model

Structure – to what extent is the current database structured similar to IDMP?	Structure different from IDMP with redesign needed	Structure similar to IDMP but adjustment needed	Structure close enough to IDMP
Terminology – to what extent is the current database and/or API terminology similar to IDMP?	Terminology different from IDMP with redesign needed	Terminology similar to IDMP but adjustment needed	Terminology close enough to IDMP
Data – to what extent does the current database hold the data IDMP covers?	Data isn't available in the SE MPA database	Some data is available and/or not always up-to-date	Data is available and kept up-to-date

Figure 9. Assessment criteria and descriptions

The first phases of the program have focused on basic information terms and logical information model regarding medicinal products and organisations.

This is reflected in the readiness results from the assessment performed in October 2020:

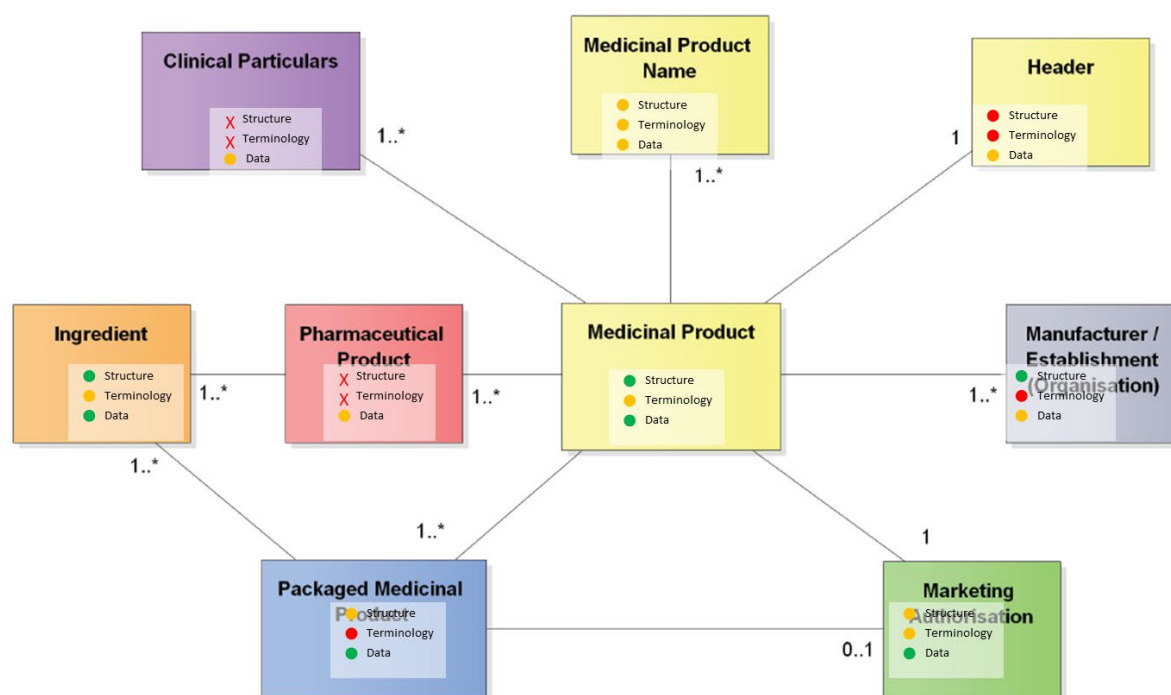


Figure 10. IDMP readiness assessment results, October 2020

In the next phase of the program the focus will be in-depth mapping and transformation of physical database schema in the database to appropriate IDMP-terms with the following goal:

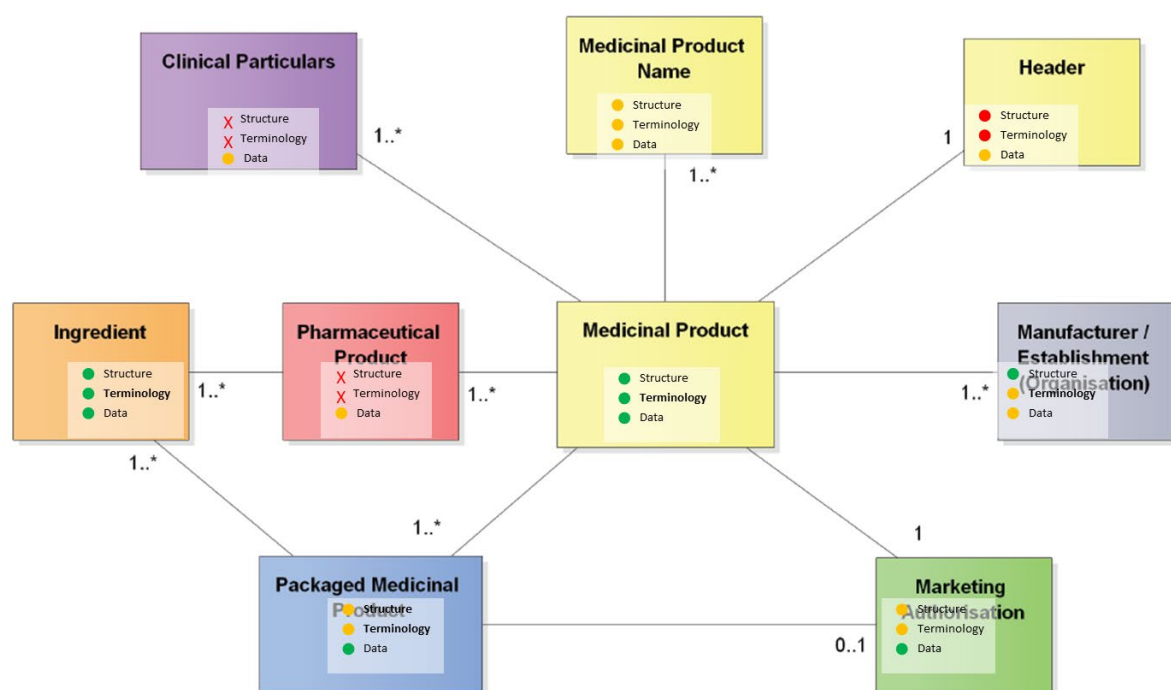


Figure 11. IDMP readiness assessment results, goal in 2023

3.5 Phased approach and transition strategy

SEMPA has planned a stepwise approach to implement IDMP where the new and old solution will live side-by-side until full de-commissioning of the legacy system LVIS GK.

Integrations are planned to secure fully functionality during the transition process.

The program and implementation is mainly divided in two parts.

Implementation part 1 2019-2022

The plan is to develop the new EIRA system with step-by-step deliveries using agile (SCRUM) methodologies.

The system should be sufficiently efficient and usable as soon as possible, have some adaptation to IDMP, be of good technical quality and have good performance, and can thus replace the entire LVIS before the end of 2022.

Part 1's driver is mainly technical needs; we will implement as much IDMP that is possible while keeping up the tempo of the transition.

Strategy:

- ▶ Create APIs, using IDMP where possible
- ▶ Use current database (with necessary additions)

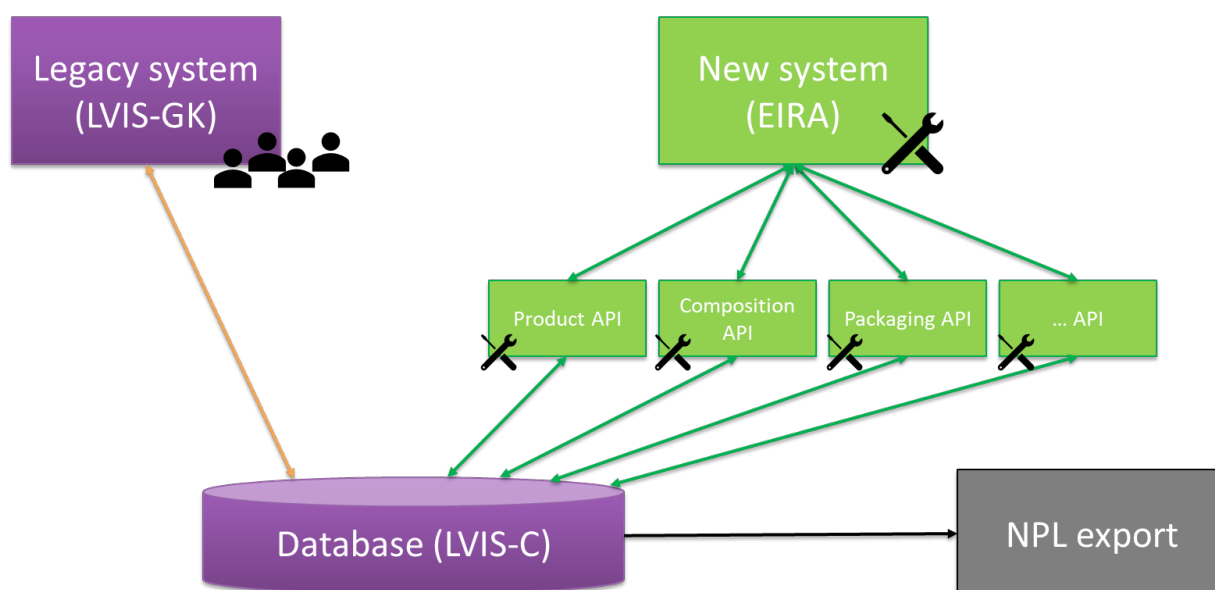


Figure 12. Implementation part 1 strategy

Implementation part 2 2023

In 2023, the plan is to make larger adjustments to IDMP, improvements in efficiency and usability, new functions that provide, for example, better traceability with version management, and a higher efficiency for users, which we did not have time to do in 2019 - 2022 due to the urgent reason to close LVIS.

The driver for part 2 is however much more unclear.

When will the IDMP structure be needed?

What is "good enough" regarding interoperable adaptation of IDMP?

Is HMA decisions and lead needed?

Strategy:

- ▶ Switch export of data (to domestic users) to use IDMP APIs
- ▶ Rearrange database to support IDMP better
- ▶ Add Pharmaceutical product, Clinical particulars

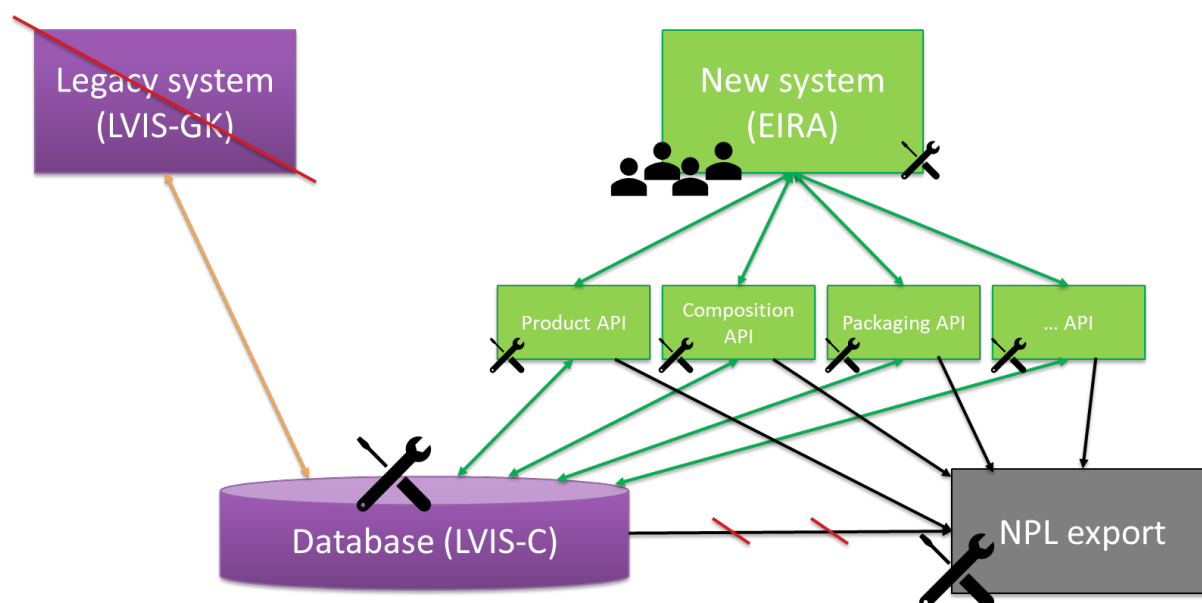


Figure 13. Implementation part 2 strategy, de-commissioned legacy system

3.6 Status and deliverables

Status as per 2020

- ▶ 2 modules out of 10 of the national system are implemented (see roadmap).
- ▶ 2 modules are approaching launch in Q1 2021.
- ▶ A national information model is implemented in order to translate and maintain terms and attributes for IDMP in SEMPAs implementation.
- ▶ SEMPAs information model is, in overall, mapped to IDMP and we are focusing on internal management of specific IDMP attributes.
- ▶ Organisation-mapping to OMS is continuous.
- ▶ Referentials are mapped to RMS and are continuously mapped.
- ▶ Substances are continuously mapped to SMS.

3.7 Plan forward

In 2021, we plan for implementation of 3 more modules and in 2022 the last 5 modules. In 2023 we plan for a larger adaptation to specific IDMP-attributes.

For Medicinal Products, the tasks include the following:

- ▶ Gap analysis of current data model against the IDMP implementation guide
- ▶ Identify needed changes
- ▶ Design the phase II data model
- ▶ Plan implementation and data migration
- ▶ Implementation of the phase II version of the medicines register

- ▶ Data migration
- ▶ Cleansing of the legacy data

In general, we continue monitoring and being aligned to EMA SPOR.

Following information is needed in order to perform remaining tasks:

- ▶ New UNICOM compatible Electronic Application Form (eAF) schema (WP3)
- ▶ SPOR implementation guideline v2

4 Best practises and lessons learned

SEMPA was one of the NCAs who hosted “Best practice and lessons learned” session for other WP4 members during the fall 2020. An overall presentation of SEMPA, the national IDMP implementation program and our experience with EMA SPOR-services was given.

4.1 Experience with SPOR API

We use the SPOR API for synchronisation of Referentials.

4.2 Experience with RMS

We have a local system for management of Referentials.

We have mapped the appropriate (approx. 30 lists) Referentials to RMS.

We have the ability to import Referentials from RMS and synchronise with local database.

We can add Referentials in an appropriate order and tempo.

4.3 Experience with SMS

Data cleansing is performed, and we have established procedures for data quality.

We are active in WP02 and contribute in that regard.

We will start appropriate activities with regard to outcomes of WP2.

Our first objective is to map veterinary substances due to UPD, in 2021 and consequently this task will help us to identify lessons learned to be implemented in the Human medicines side.

We need to define objectives and a transition strategy for our future system, based on outcomes from WP2, EU-SRS, SMS and eAF. We can start appropriate activities when the EU-system and its data is of certain quality.

4.4 Experience with OMS

We are waiting for more results from UPD in order to start appropriate activities.

We are preparing to be ready for exporting products data to PMS (UPD) during 2021.

5 Challenges, risks, and mitigations

The Covid-19 pandemic situation puts big pressure on the NCAs in general and affects SEMPA in many ways.

- ▶ Business resources are prioritised to Covid-19 related tasks
 - ▶ Vaccine assessment
 - ▶ Pharmacovigilance
 - ▶ Communication and information to the public and other stakeholders
 - ▶ Shortages handling
- ▶ New assignments from the government related to Covid-19
 - ▶ Shortages monitoring
 - ▶ Electronic reporting of suspected Adverse Reactions on Covid-19 vaccines
- ▶ The transition to home-office challenge the efficiency of the organisation

Another challenge is the Internal prioritization of resources and finances in a competitive environment

- ▶ Several large areas of internal legacy systems require mitigation of risks
- ▶ New regulations are driving Business Change
 - Veterinary legislation
 - Adverse Drug Reaction reporting
 - Medical Devices
 - Clinical Trials

The overall success regarding IDMP is coupled to interoperability, and interoperability resides on a collective goal of common structure. Transition to IDMP means investment in people and finances in a competitive environment. It must therefore be based on crisp demand and clarity from EMA and HMA, as a collective effort for all MS (Member States), not only those MS that participates in UNICOM.

The success of the SEMPA IDMP implementation is also highly dependent on factors outside the control of SEMPA

- ▶ eAF format, structure and content must be decided (WP2)
- ▶ Process for validation of legacy data in PMS needs to be clarified (EMA TOM)
- ▶ Process for importing of Organisation data into OMS
 - ▶ For example, how will the 60% of Organisations regarding veterinary products that currently does not exist in OMS, be registered in OMS?
 - ▶ Should SEMPA manage it, will EMA do it or should the organisations do it?